

## **REMARKS/ARGUMENTS**

Applicants have reviewed and considered the Final Office Action mailed on May 28, 2008, and the reference cited therewith. Claims 1-15 are currently pending in the application. Reconsideration and allowance of all pending claims are respectfully requested in view of the following remarks.

### *Claim Rejections – 35 U.S.C. § 112*

The Examiner rejects claims 1-13 under 35 U.S.C. § 112, first paragraph, as non-enabling. In particular, the Examiner states that:

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a shut-off valve that automatically closes the outlet from the canister when the canister is full (Specification, Page 4, lines 8-10), does not reasonably provide enablement for any structural features or processes which are responsible for this automatic closure of the shut-off valve in response to the canister being full. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Applicant states on page 4 of the specification that the canister may be of conventional design having a shut-off valve which automatically closes once the canister is full. The conventional design is interpreted herein by examiner to refer to only the structure of the canister, which includes the shut-off valve, as such shut-off valves are conventional in the wound canister art. However, a shut-off valve must either be operated manually or automatically by an external input to convert from the open state to the closed state, such as manual force by a human operator or automated mechanical structure, or an electronic signal from an external control. An automatic shut-off valve is not conventional, and there is no further description of the valve or the manner in which this automatic closure in response to the canister being full in the disclosure. (Office Action dated May 28, 2008, page 4).

The enablement requirement of 35 U.S.C. § 112, first paragraph, requires that the specification describe how to make and use the invention. The analysis of whether a claim is enabled by the disclosure requires a determination of whether that disclosure, when originally filed, contained sufficient information regarding the subject matter of the claims to enable a person of skill in the art to make and use the claimed invention. The

standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which presented the question: is the experimentation needed to practice the invention undue or unreasonable?" MPEP 2164.01. Under this standard, "not everything necessary to practice the invention need be disclosed." MPEP 2164.08 (citing *In re Buchner*, 989 F.2d 660, 661 (Fed. Cir. 1991).

The Examiner asserts that the feature of a "canister having a shut-off valve which closes an outlet from the canister in response to the collection canister being full" is not enabled under 35 U.S.C. § 112, first paragraph. Specifically, the Examiner asserts that the specification "does not reasonably provide enablement for any structural features or processes which are responsible for this automatic closure of the shut-off valve in response to the canister being full." (Office Action dated May 28, 2008, page 4).

Applicants respectfully traverse the enablement rejection as being wholly without merit. Undue experimentation is not required to practice this claimed feature because Applicants' patent application teaches and enables both the claimed shut-off valve, as well as the manner of determining when the canister is full. For example, at least the following portions of the Specification enable a shut-off valve that closes when the canister is full:

According to one aspect of the present invention there is provided apparatus for applying negative pressure therapy to a wound site, said apparatus comprising an open celled foam pad for application to the wound, a suction tube connecting the foam pad to a collection canister, said canister having a shut-off valve which closes the outlet from the canister when it is full. (Specification, page 2, lines 13-17, emphasis added).

The canister (3) may be of conventional design having a shut-off valve (shown diagrammatically at (140), which automatically closes once the canister is full. (Specification, page 4, lines 8-10, emphasis added).

The claimed shut-off valve is also recited in original claim 1, and illustrated in Figure 1 as reference numeral 140. Applicants' patent application also enables determining when the canister is full, which is the condition upon which the shut-off valve is closed. For example, at least the following portion of the Specification enables determining when the canister is full:

The canister full situation is detected by noting a pressure differential between transducer (20) and transducer (21), or by means of a separate fluid level sensor. Pressure detection at the wound site via the transducer (20) also indicates whether there is a pressure leak or no therapy. A custom-made canister (32) may include means for sensing electronically when the canister is full and must be replaced, e.g. by capacitance measuring means (34). (Specification, page 6, lines 16-21).

Enabling support for determining when the canister is full can also be found in the Applicants' patent application on at least page 2, lines 22 - page 3, line 4; page 7, lines 3-18; and originally filed claim 8. Because at least these portions of the Applicants' patent application teach examples of structural features or processes associated with the claimed feature, no undue experimentation is required by a person of ordinary skill in the art to make and use the claimed invention.

The Examiner appears to suggest that some additional disclosure or teaching is required to enable a person of ordinary skill in the art to select a valve that would close an outlet in response to a determination that the collection canister is full. Surely this is not the case. The originally-filed specification provides ample description of valves and their relation to the canister. The specification also describes in detail examples of components and methods for detecting the fill status of the canister. It is clear that a person of ordinary skill in the art of the claimed invention would not need to undertake undue experimentation to make and use the claimed elements which the Examiner has identified.

For the above-mentioned reasons, Applicants respectfully request withdrawal of the enablement rejection of claims 1-13.

*Claim Rejections – 35 U.S.C. § 103*

The Examiner rejects claims 14 and 15 under 35 U.S.C. § 103 as obvious over International Publication Number WO 96/05873 (hereinafter "Lina"). This rejection is respectfully traversed. With respect to Figure 14, the Examiner states that:

With respect to claim 14: Lina teaches an apparatus for applying negative pressure therapy to a wound site, the apparatus comprising: an open-celled foam pad 36 for application to the wound

site; a suction tube in the collective form of hoses 37,38 connecting the foam pad 36 to a collection canister 19; a pressure regulator in the form of restrictor 89 fluidly connected between the canister 19 and vacuum pump 84; and a processor in the form of microcontroller 72 in electronic communication with the pressure regulator 89 to regulate the pressure from said vacuum pump 84 to the collection canister 19.

Lina does not explicitly teach a wall suction source, however a wall suction source is an example of a vacuum pump and performs a substantially identical function to the vacuum pump taught by Lina. Thus, it would be obvious to one of ordinary skill in the art to substitute a wall suction source for the vacuum pump taught by Lina with a reasonable expectation of success to ensure that the suction function of the instant apparatus is preserved while the device is stationary or when the device is used portably with the instant vacuum pump. (Page 7, 113, Page 17, ¶¶ 2,3). (Office Action dated May 28, 2008, pages 5 and 6).

As an initial matter, the Examiner incorrectly states that "Applicant does not appear to argue claims 14 and 15," and that the "failure to address the rejection of claims 14 and 15 is regarded as a concession that the rejections are proper and are thus maintained herein." (Office Action dated May 28, 2008, page 3). On the contrary, Applicants addressed claims 14 and 15 on page 23 of the Response to the Office Action dated May 28, 2008. Thus, Applicants make no concession that any of the Examiner's rejections are proper.

No *prima facie* obviousness rejection may be stated against claims 14 and 15 because Lina fails to teach or suggest all of the features of claims 14 and 15. Furthermore, Lina may not be modified in the manner proposed by the Examiner because the Examiner fails to state a sufficient reason to modify Lina under *KSR Int'l. Co. v. Teleflex, Inc.*, 127 S.Ct. 1727 (U.S. Apr. 30, 2007). In addition, the modification of Lina proposed by the Examiner renders Lina unsatisfactory for Lina's intended purpose.

I. Lina Fails to Teach or Suggest All of the Features of Claim 14

The Examiner bears the burden of establishing a *prima facie* case of obviousness based on prior art when rejecting claims under 35 U.S.C. § 103. *In re Fritch*, 972 F.2d 1260, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992). Additionally, the prior art reference (or references when combined) must teach or suggest all the claim

limitations. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Therefore, the Examiner fails to state a *prima facie* obviousness rejection if the proposed combination does not teach or suggest all of the features of the claimed invention.

A *prima facie* obviousness rejection cannot be stated because Lina does not teach or suggest all of the features of claim 14. Specifically, Lina fails to teach or suggest at least (1) a pressure regulator fluidly connected between the canister and a wall suction point, and (2) a processor in electronic communication with the pressure regulator to regulate the pressure from said wall suction point to the collection canister.

I.A. Lina fails to teach or suggest a pressure regulator fluidly connected between the canister and a wall suction point

Lina fails to teach or suggest a pressure regulator fluidly connected between the canister and a wall suction point. As an initial matter, the Examiner admits that "Lina does not explicitly teach a wall suction source." (Office Action dated May 28, 2008, page 5). Additionally, because Lina is devoid of disclosure in this regard, nothing in Lina suggests this claimed feature.

Although the Examiner cites no portions of Lina with respect to the feature of a wall suction point, the Examiner refers to the vacuum pump disclosed in Lina as suggesting this claimed feature. Lina's vacuum pump is described in the following portion of Lina:

As illustrated in Figures 1 and 2, front housing 11 and rear housing 12 connect together using any suitable means such as screws and fasteners to provide wound closure vacuum pump 10 with a small, compact, and easily portable carrying case. Consequently, front housing 11 and rear housing 12 connect together to form handle 13 that permits easy carrying of wound closure apparatus 10. Except as maybe otherwise evident from this description, the carrying case of vacuum pump 10 is substantially as described and shown in WIPO Design No. DM/032185.

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As illustrated in Figures 2, 4 and 6, canister 19 includes outlet 44 that mounts over port 45 to permit wound closure apparatus 10 to draw wound fluids into canister 19. Outlet 44 is cylindrically shaped and formed as an integral part of back wall 22 by outer wall 33 and inner wall 50 which are interconnected by end wall 34. Passageway 52, defined in part by interior wall 50 and in part by filter cap 49,

provides the actual conduit for outlet 44 between the interior and exterior of canister 19. The placement of canister 19 within recess 18 such that outlet 44 resides over port 45 couples canister 19 to a vacuum pump. The vacuum pump removes air from canister 19 to create vacuum pressure within canister 19. That vacuum pressure is then transmitted to a wound site through hoses 37 and 38, thereby not only enabling therapeutic use of system 10, but also tending to promote wound drainage. Any wound drainage fluid is then drawn through pad 36 and hoses 37 and 38 into canister 19. (Lina, page 4, last paragraph and page 9, paragraph 2).

The cited portion discloses a vacuum pump that is contained in an easily portable carrying case. The vacuum pump removes air from canister 19 via port 45 and canister outlet 44. On the other hand, claim 14 recites the feature of a pressure regulator fluidly connected between the canister and a wall suction point. The cited portion differs from the claimed feature because the cited portion nowhere mentions a wall, let alone that the disclosed vacuum pump is a wall vacuum pump. Therefore, Lina fails to teach or suggest this claimed feature.

In response to the facts established above, the Examiner asserts that:

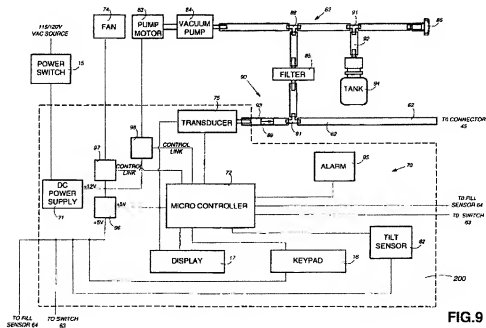
Lina certainly suggest a tube connecting to a wall suction point. the fact that the Lina device is portable in no way precludes or teaches away from it from being used in a stationary capacity, e.g. adjacent a hospital bed. The device of Lina simply has the advantage of having its won suction pump therein for portability when needed or desired. The fact that wall is not mentioned is immaterial. The instant device is a wound drainage device, and wounds are commonly drained in enclosed sterile environments (e.g. hospitals) having walls. One of ordinary skill in the art would certainly be motivated to use the instant wound drainage device in a hospital or clinic environment having walls and wall suction points. (Office Action dated May 28, 2008, pages 2 and 3).

The Examiner maintains that a wall suction source is suggested by Lina, but again fails to cite any portions of Lina that teach or suggest a wall suction source. Indeed, so such portion of Lina exists. Also, as shown below, the inclusion of a wall suction source in Lina's apparatus would detract from the intended purpose of Lina. Thus, Lina fails to teach or suggest this claimed feature.

I.B. Lina fails to teach or suggest a processor in electronic communication with the pressure regulator to regulate the pressure from said wall suction point to the collection canister

Lina fails to teach or suggest a processor in electronic communication with the pressure regulator to regulate the pressure from said wall suction point to the collection canister. The Examiner cites a restrictor 89 in Lina against the claimed feature of a pressure regulator. The only portions of Lina that disclose the restrictor 89 are as follows:

Line 62 also includes T-connector 91 to connect it with line 92. Line 92 is connected to tank 94 which acts as a damper to pressure changes in line 62. This dampening effect, facilitated by restrictor 89 in line 93 between transducer 75 and T-junction 91, causes the pressure measured by transducer 75 to be an accurate indication of actual wound site pressure. Transducer 75 communicates with line 62 via line 93 to measure tank 94 pressure and produce an electrical signal representative of that pressure. Transducer 75 outputs its pressure signal to microcontroller 72. (Lina, page 17, lines 9-16).



The cited portions disclose that the restrictor 89 facilitates a dampening effect in a line 93. On the other hand, claim 14 recites the feature of a processor in electronic communication with the pressure regulator to regulate the pressure from said wall suction point to the collection canister. Even assuming, *arguendo*, that the restrictor 89 is the same as the pressure regulator, as claimed, the cited portions still differ from the claimed feature because the cited portions nowhere teach or suggest that the restrictor 89 is in "electronic communication" with the microcontroller 72.

Furthermore, as shown in Section I.A., Lina fails to teach or suggest the feature of a wall suction point. Therefore, Lina also fails to teach or suggest the feature of a processor in electronic communication with the pressure regulator to regulate the pressure from said wall suction point to the collection canister. Thus, Lina fails to teach or suggest this claimed feature.

## II. The Examiner Fails to State a Sufficient Reason to Modify the Reference

The Examiner bears the burden of establishing a *prima facie* case of obviousness based on prior art when rejecting claims under 35 U.S.C. § 103. *In re Fritch*, 972 F.2d 1260, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992). The scope and content of the prior art are... determined; differences between the prior art and the claims at issue are... ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or non-obviousness of the subject matter is determined. *Graham v. John Deere Co.*, 383 U.S. 1 (1966). Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. *KSR Int'l. Co. v. Teleflex, Inc.*, 127 S.Ct. 1727 (U.S. Apr. 30, 2007). Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *Id.* (citing *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006)).



In the case at hand, no *prima facie* obviousness rejection can be stated because the Examiner failed to state a sufficient reason to modify Lina in light of the differences between Lina and claim 14. Specifically, as shown in Section I, Lina fails to teach or suggest (1) a pressure regulator fluidly connected between the canister and a wall suction point, and (2) a processor in electronic communication with the pressure regulator to regulate the pressure from said wall suction point to the collection canister. Because Lina fails to teach or suggest at least these claimed features, major differences exist between the cited reference and claim 14 under the *Graham v. John Deere Co.* inquiry set forth above.

In light of these major differences, the Examiner fails to provide a sufficient reason to modify Lina such that Lina teaches or suggests a wall suction point. In particular, the Examiner states that:

Lina does not explicitly teach a wall suction source, however a wall suction source is an example of a vacuum pump and performs a substantially identical function to the vacuum pump taught by Lina. Thus, it would be obvious to one of ordinary skill in the art to substitute a wall suction source for the suction pump taught by Lina with a reasonable expectation of success to ensure that the suction function of the instant apparatus is preserved while the device is stationary or when the device is used portably with the instant vacuum pump. (Office Action dated May 28, 2008, pages 5 and 6).

The Examiner proposes modifying Lina "to ensure that the suction function of the instant apparatus is preserved while the device is stationary or when the device is used portably with the instant vacuum pump." However, the Examiner fails to provide a sufficient reason to modify Lina because Lina already achieves the advantage set forth by the Examiner. In particular, Lina's wound closure apparatus may be used as a portable device, as well as a stationary device. For example, Lina states that "[a]rm 14 and its corresponding arm may also be used to permit hanging of apparatus 10 from a hospital bed foot board." Because Lina already achieves the advantage cited by the Examiner, one of ordinary skill in the art would not be motivated to modify Lina as proposed by the Examiner, and the cited advantage cannot provide a rational underpinning to support a legal conclusion of obviousness. Thus, the Examiner's reason for modifying Lina provides insufficient basis for modifying Lina in the manner

proposed by the Examiner, especially in light of the major differences that exist between the cited reference and claim 14. Accordingly, no *prima facie* obviousness rejection has been stated against claim 14.

In response to the facts established above, the Examiner asserts that "pages 17 and 18 appear to be simply a repetition of case law regarding obviousness with no substantive argument." (Office Action dated May 28, 2008, page 3). On the contrary, pages 17 and 18 of the Response to the Office Action dated November 14, 2007 shows the major differences that exist between the prior art and the claims at issue. As stated above, *Graham v. John Deere Co.*, which has been upheld in *KSR Int'l. Co. v. Teleflex, Inc.*, requires that the differences between the prior art and the claims at issue be ascertained to lay the background for an obvious inquiry. The Examiner fails to state a sufficient reason to modify Lina in light of these differences. The Examiner also asserts that:

Applicant argues on page 19 that Lina already achieves all of the advantages of the claimed invention and thus there would be no motivation to modify the device of Lina to permit hanging the apparatus from a foot board. Examiner has reviewed the previous Office action mailed November 14, 2007 several times and not found this statement, therefore the argument will not be addressed. (Office Action dated May 28, 2008, page 3).

The Examiner has incorrectly summarized Applicants arguments in the previous Response. As a first matter, Applicants nowhere stated that "Lina already achieves all of the advantages of the claimed invention." Instead, Applicants showed that Lina already achieved the advantage cited by the Examiner, and therefore one of ordinary skill in the art would not be motivated to modify Lina as proposed by the Examiner. As a second matter, the Examiner asserts that she was unable to find the statement pertaining to hanging the apparatus of Lina from a foot board in the Office Action dated November 14, 2007. However, Applicants' previous Response nowhere quoted an Office Action as containing this statement. Instead, the previous Response stated: "For example, Lina states that '[a]rm 14 and its corresponding arm may also be used to permit hanging of apparatus 10 from a hospital bed foot board.'" (Response dated February 12, 2008, first emphasis added). Applicants' quoted this statement from Lina

to show that Lina already achieves the advantage cited by the Examiner. Accordingly, no *prima facie* obviousness rejection has been stated against claim 14.

III. The Proposed Modification Renders Lina Unsatisfactory for Lina's Intended Purpose

The Examiner has failed to state a *prima facie* obviousness rejection because the proposed modification renders Lina unsatisfactory for Lina's intended purpose. "If [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." MPEP 2143.01 (citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)).

An intended purpose of Lina is to provide self-contained wound closure apparatus that may be transported in a small, compact, and portable carrying case. Lina describes this intended purpose in the following portion, which is reproduced below along with Figure 1:

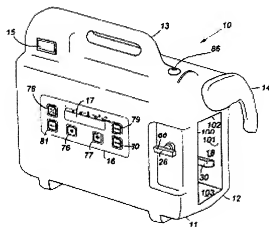


FIG.1

It is another object of the present invention to render technology like that disclosed in WO 93/09727 available in a convenient, compact and self-contained, efficient and economically feasible system. It is also an object to optimize the safety and effectiveness of such a device, particularly from an infection control standpoint.

....  
As illustrated in Figures 1 and 2, front housing 11 and rear housing 12 connect together using any suitable means such as screws and fasteners to provide wound closure vacuum pump 10 with a small, compact, and easily portable carrying case. Consequently, front housing 11 and rear housing 12 connect together to form handle 13 that permits easy carrying of wound closure apparatus 10. Except as maybe otherwise evident from this description, the carrying case of vacuum pump 10 is substantially as described and shown in WIPO Design No. DM/032185. (Lina, page 3, paragraph 3 and page 4, last paragraph, emphasis added).

The Examiner's proposed modification renders Lina unsatisfactory for Lina's intended purpose because the Examiner proposes to "substitute a wall suction source for the suction pump taught by Lina," thereby defeating Lina's purpose of providing a self-contained and portable wound closure apparatus. Specifically, Lina's wound closure apparatus would cease to be self-contained and portable if the apparatus required a wall vacuum pump that was located outside of housing 11. Thus, no *prima facie* obviousness rejection has been stated against claim 14.

#### IV. Conclusion as to Obviousness

As shown above, the Examiner fails to state a *prima facie* obviousness rejection against claim 14. In addition, no *prima facie* obviousness rejection can be stated against claim 15 at least by virtue of claim 15's dependency on claim 14. Claim 15 also claims other additional combinations of features not taught or suggested by Lina.

**CONCLUSION**

If a Petition for Extension of Time under 37 C.F.R. 1.136(a) is required, the petition is herewith made. The Commissioner is authorized to charge any fees that may be required, or credit any overpayment made with this Office Action, to Deposit Account Number 19-3140.

In light of all the foregoing, believing that all things raised in the Office Action have been addressed, Applicant respectfully requests reconsideration of the prior rejections and objections, as well as allowance of the claims and passage of the application to issue. If the Examiner would care to discuss any remaining matters by phone, Applicant invites the Examiner to contact the undersigned at (214) 259-0907.

Respectfully submitted,



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